

Attorneys for Defendants

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Defendants Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare (a Division of Orchid Chemicals & Pharmaceuticals Ltd.), Orchid Pharmaceuticals Inc., and Organus Pharma, Inc. (collectively "Defendants"), by and through their attorneys, hereby jointly respond to the complaint of plaintiff Hoffmann-La Roche Inc. ("Plaintiff" or "Roche"), as follows:

NATURE OF THE ACTION

1. Defendants admit that plaintiff commenced this action to enforce its purported patent rights under the Food and Drug and the Patent Laws of the United States, and deny the remaining allegations of paragraph 1 of the complaint.

PARTIES

2. Defendants are without information or knowledge sufficient to admit or deny the allegations of paragraph 2, and therefore deny those allegations.

3. Defendants admit the allegations of paragraph 3.

4. Defendants admit the allegations of paragraph 4.

5. Defendants admit the allegations of paragraph.

6. Defendants admit that Defendant Organus Pharma, Inc. is a New Jersey Corporation with its principal place of business at 116 Village Boulevard, Suite 200, Princeton, New Jersey, 08540, and deny the remaining allegations of paragraph 6.

7. Defendants admit that the complaint refers to them collectively as Orchid, as stated in paragraph 7.

JURISDICTION AND VENUE

8. Defendants admit the allegations of paragraph 8.

9. Defendants admit that Orchid Chemicals & Pharmaceuticals Ltd. directly, or through subsidiaries or affiliates, markets and sells generic drugs throughout the United States and in this judicial district. However, Defendants deny the remaining allegations made in paragraph 9.

10. Defendants admit that this Court has personal jurisdiction, and deny the remaining allegations of paragraph 10.

11. Defendants admit the allegations of paragraph 11.

STATEMENT OF FACTS

12. Defendants admit that they seek approval from the United States Food and Drug Administration ("FDA") to market a generic version of Roche's Boniva Once-Monthly drug product, but are otherwise without information or knowledge sufficient to admit or deny the remaining allegations made in paragraph 12 and therefore deny those allegations.

13. Paragraph 13 sets forth an interpretation of the law to which no response is required; to the extent that a response to the allegations of paragraph 13 is required, Defendants deny them.

14. Defendants are without information or knowledge sufficient to admit or deny the allegations of paragraph 14, and therefore deny those allegations.

15. Paragraph 15 sets forth an interpretation of the law to which no response is required; to the extent that a response to the allegations of paragraph 15 is required, Defendants deny them.

16. Paragraph 16 sets forth an interpretation of the law to which no response is required; to the extent that a response to the allegations of paragraph 16 is required, Defendants deny them.

17. Defendants admit that Orchid has filed ANDA No. 78-998 with the FDA for approval to market a 150 mg generic version of Roche's Boniva Once-Monthly drug product, and deny the remaining allegations of paragraph 17.

18. Defendants admit the allegations of paragraph 18.

19. Defendants admit the allegations of paragraph 19.

20. Defendants admit that there is a justiciable controversy between Roche and Defendants with respect to Roche's alleged patent rights, and deny the remaining allegations of paragraph 20.

COUNT I

21. Defendants repeat their answers to the allegations of paragraphs 1 through 20 of the complaint as if fully set forth at length here.

22. Defendants admit that the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,192,938 (the "'938 patent") and that a true and correct copy of the '938 patent is attached to the complaint, but deny the remaining allegations of paragraph 22.

23. Defendants are without information or knowledge sufficient to admit or deny the allegations of paragraph 23, and therefore deny those allegations.

24. Defendants are without information or knowledge sufficient to admit or deny the allegations of paragraph 24, and therefore deny those allegations.

25. Defendants admit that the '938 patent is listed in the Orange Book and that the Orange Book is maintained by the FDA, but deny the remaining allegations of paragraph 25.

26. Defendants admit that they included a Paragraph IV certification with their ANDA alleging that the '938 patent is invalid or will not be infringed, but deny the remaining allegations of paragraph 26.

27. Defendants deny the allegations of paragraph 27.

28. Defendants admit that a justiciable case or controversy exists between Roche and Defendants with respect to the '938 patent, but deny the remaining allegations of paragraph 28.

29. Defendants deny the allegations of paragraph 29.

30. Defendants deny the allegations of paragraph 30.

31. Defendants deny the allegations of paragraph 31.

32. Defendants deny the allegations of paragraph 32.

COUNT II

33. Defendants repeat their answers to the allegations of paragraphs 1 through 32 of the complaint as if fully set forth at length here.

34. Defendants admit that the PTO issued U.S. Patent No. 6,294,196 (the "'196 patent") and that a true and correct copy of the '196 patent is attached to the Complaint, but deny the remaining allegations of paragraph 34.

35. Defendants are without information or knowledge sufficient to admit or deny the allegations of paragraph 35, and therefore deny those allegations.

36. Defendants admit that the '196 patent is listed in the Orange Book and that the Orange Book is maintained by the FDA, but deny the remaining allegations of paragraph 34.

37. Defendants admit that they included a Paragraph IV certification with their ANDA alleging that the '196 patent is invalid or will not be infringed, and deny the remaining allegations made in paragraph 37.

38. Defendants admit that a justiciable case or controversy exists between Roche and defendants with respect to the '196 patent, and deny the remaining allegations of paragraph 38.

39. Defendants deny the allegations of paragraph 39.

40. Defendants deny the allegations of paragraph 40.

41. Defendants deny the allegations of paragraph 41.

42. Defendants deny the allegations of paragraph 42.

43. To the extent not explicitly admitted above, Defendants deny each allegation of the complaint.

FIRST AFFIRMATIVE DEFENSE

The complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

One or more claims of the '938 and '196 patents are invalid for failing to satisfy one or more requirements of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE

Defendants do not infringe, have not infringed, are not inducing, contributing to, or cooperating in the infringement of, and have not induced, contributed to, or cooperated in the infringement of, the '938 and '196 patents.

FOURTH AFFIRMATIVE DEFENSE

The complaint should be dismissed because the '938 and '196 patents are not properly listed in the Orange Book for Roche's Boniva Once-Monthly drug product.

WHEREFORE, Defendants Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare (a Division of Orchid Chemicals & Pharmaceuticals Ltd.), Orchid Pharmaceuticals Inc., and Orgenus Pharma, Inc. demand judgment in their favor, dismissing the complaint with prejudice, together with costs of suit, and such other and further relief as the Court may deem just and appropriate.

COUNTERCLAIM

Defendants/counterclaimants Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare (a Division of Orchid Chemicals & Pharmaceuticals Ltd.), Orchid Pharmaceuticals Inc., and Orgenus Pharma, Inc., as and for their counterclaim against plaintiff, state and allege as follows:

Nature of the Action

1. This counterclaim seeks a declaratory judgment of non-infringement and invalidity of the '938 and '196 patents asserted by plaintiff in this action. Defendants seek judgment under the patent laws of the United States, 35 U.S.C. § 101, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 and 2202.

The Parties

2. Defendant/counterclaimant Orchid Chemicals & Pharmaceuticals Ltd. is an public limited liability company organized under the laws of India, which maintains its principal place of business at Orchid Towers, No. 313, Valluvar Kottam Road, Nungambakkam, Chennai – 600 034, Tamil Nadu, India.

3. Defendant/counterclaimant Orchid Healthcare is an unincorporated division of Orchid Chemicals & Pharmaceuticals Ltd., which maintains a place of business at

Plot Nos. B3-B6 and B11-B-14, Sipcot Industrial Park, Irungattukottai, Kancheepuran District – 602 105, India.

4. Defendant/counterclaimant Orchid Pharmaceuticals Inc. is a corporation organized under the laws of Delaware and maintains its principal place of business at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

5. Defendant/counterclaimant Orgenus Pharma Inc. is a corporation organized under the laws of New Jersey and maintains its principal place of business at 116 Village Boulevard, Suite 200, Princeton, New Jersey 08540.

6. Plaintiff/counterclaim-defendant Hoffmann La Roche Inc. is a corporation organized under the laws of New Jersey and maintains its principal place of business at 340 Kingsland Street, Nutley, New Jersey 07110

Jurisdiction and Venue

7. This Court has subject matter jurisdiction over this counterclaim pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, justiciable controversy exists within this jurisdiction regarding, *inter alia*, the validity of the '938 and '916 patents and the technical act of infringement of Defendants/counterclaimants' generic Boniva products, as evidenced by the filing of Roche's complaint and Roche's listing of the '938 and '916 patents in the Orange Book with respect to Roche's Boniva products.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(d).

COUNT I
(Non-Infringement)

9. Defendants/counterclaimants do not infringe and have not infringed the '938 or '196 patents directly, contributorily or by inducement.

COUNT II
(Invalidity)

10. One or more of the claims of the '938 and '196 patents are invalid because they fail to satisfy one or more of the conditions for patentability under Title 35 of the United States Code, including one or more of the following: 35 U.S.C. §§102, 103, and/or 112.

WHEREFORE, Defendants/counterclaimants respectfully pray for judgment:

- a. Declaring the '938 and 528 patents invalid and/or not infringed by Defendants/counterclaimants;
- b. Awarding Defendants/counterclaimants such other and further relief as the Court may deem just and appropriate.

GRAHAM CURTIN, P.A.
Attorneys for Defendants

By: _____


CHARLES QUINN (CQ 8940)

Dated: November 8, 2007
Morristown, N.J.

Of Counsel:


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CERTIFICATE OF SERVICE

I hereby certify that on this day I caused the attached Answer and Counterclaim to be served by ECF electronic filing and by regular mail upon:

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